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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,875	10/30/2003	Tomoaki Hoshino	032079	6666

38834 7590 02/10/2005

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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/695,875	HOSHINO	
	Examiner	Art Unit	
	Yunsoo Kim	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 7-9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 7-9 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/18/04,10/20/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Yunsoo Kim, Group Art Unit 1644, Technology Center 1600

2. Claims 7-9 are pending.

3. Applicant's election without traverse of Group I, claims 7-9 drawn to an agent reads on using NK-cell antibodies, in the reply filed on 12/2/04 is acknowledged.

Claims 7-9 drawn to an agent that reads on using anti-NK cell antibodies are under consideration in the instant application.

4. Applicants' claim for foreign priority under 35.U.S.C. 119 (a)-(d) is acknowledged.

Applicant is invited to provide certified copies of priority documents.

5. Applicants' IDS filed on 3/18/04 and 10/20/04 are acknowledged.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 7-9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an anti-NK1.1 antibody agent for treating dermatitis by suppressing a cell having an NK 1.1 antigen, does not reasonably provide enablement for any agent or substance preventing dermatitis by suppressing a cell having an NK1.1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and /or use the invention commensurate in scope with these claims.

The specification does not enable one of skill in the art to practice the invention as claimed without undue experimentation. Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed.Cir.1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of the skilled in the art to practice the claimed invention.

There is insufficient guidance in the specification as filed as to how the skilled artisan would make and use the anti-NK1.1 antibody agent in "preventing" dermatitis and which "agent or substance" to select to treat dermatitis by suppressing a cell having an NK1.1. As an agent can be read on any nucleic acid, protein, soluble receptor, ligand, and small organic molecule, specification fails to provide sufficient guidance to direct a person of skilled in the art to make and select a particular agent to achieve the intended use of the claimed invention without undue experimentation.

Hoare et al. (Health Technology Assessment 2000; Vol. No. 37) teach that there is reasonable evidence to support oral cyclosporin and corticosteroids therapies for "treatment" of atopic eczema (see Result); however, there is not enough support for disease prevention, oral predinisolone and oral azathioprine therapies (see Result and conclusion).

Minor structural differences among structurally related compounds or compositions can result in substantially different pharmacological activities. Therefore structurally unrelated agent comprising antibodies, protein, peptides, nucleic acids, and other organic compounds would be expected to have greater differences in their activities.

Furthermore, Applicants have no working examples demonstrating anti-NK-antibody preventing dermatitis by suppressing a cell having an NK1.1 antigen and any agent to treat dermatitis other than anti-NK1.1 antibody.

To summarize, reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view or the quantity of experimentation necessary, the limited working example, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breath of the claims, it would take undue trials and errors to practice the claimed invention.

8. Claims 7-9 are rejected under 35.U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed, had possession of the claimed invention.

There is insufficient written description encompassing "agent" because any nucleic acid, protein, soluble receptor, ligand and small organic molecule of different chemical or physical properties of agent is not set forth in the specification as filed, commensurate in scope with the claimed invention. Claims 7-9 read on any agent but Applicant fails to disclose even a single species within the genus claimed other than anti-NK1.1 antibody One species of antibody does not provide written description for the genus, agent. Therefore, Applicant does not possess of scope of claimed invention. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of use.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Nickloff (WO 00/02923, IDS reference AF).

Nickloff teaches a composition that altering the activation of NK-T cells (see p. 20, lines 10-18) or inhibiting (see claims 1-7), and the further use of the composition to treat dermatitis and alopecia (see p. 18, lines 5-19). Nickloff further teaches the use of antibody to treat dermatitis and alopecia by inhibiting the NK cell activation (see claims 1-9).

As acknowledged in specification of instant application on p.12, lines 1-4, human NK 1.1 antigen is CD161, and reference teachings read on CD161 of NK cell surface molecule; thus, the reference teaching anticipates the instant claimed invention.

11. No claims are allowable.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-

direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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February 2, 2005

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